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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,790	04/11/2001	Michael J. Lodes	210121.512	1956

500 7590 12/10/2002

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EXAMINER	
WHISENANT, ETHAN C	
ART UNIT	PAPER NUMBER
1634	12

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/833,790	LODES ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *2,5-7,9,10,12,13 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 and 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election of Group I (Claims 1, 3-4, 8 11 and 14 & SEQ ID NO: 365) in the response filed 18 SEP 02 (i.e. paper Nos. 9-11) is acknowledged. Accordingly, Claims 2, 5-7, 9-10, 12-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is noted that the applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, therefore the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement has been reconsidered, is deemed proper and is therefore, herein made **FINAL**. An action on **Claim(s) 1, 3-4, 8, 11 and 14 as they relate to SEQ ID NO: 365** follows.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim Rejections - 35 USC § 101

4. **Claim(s) 1, 3-4, 8 11 and 14** is/are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claimed cDNA compound is not supported by a specific asserted utility because the use of SEQ ID NO: 365 or a fragment thereof is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid being claimed. Further, the claimed cDNA compound is not supported by a substantial utility because the specification only supports the use of the cDNA for making the corresponding protein. In this case the protein set forth in SEQ ID NO: 366. Once the protein is obtained, the protein would be used in research to functionally characterize the protein. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In the instant case the protein that is to be produced as a final product resulting from processes involving the claimed cDNA does not have an asserted or identified specific and substantial utility. The research contemplated by applicants to characterize the potential protein product, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the cDNA compound such that another non-asserted utility would be well established for the compound

35 USC § 112 - 1ST PARAGRAPH

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH

6. **Claim(s) 1, 3-4, 8,11 and 14** is/are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reason(s) set forth above, one skilled in the art would not know how to use the claimed invention without undue experimentation.

35 USC § 112- 2ND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

8. **Claim(s) 1, 3-4, 8, 11 and 14** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim(s) 1, 3-4, 8, 11 and 14 recite limitations that have been withdrawn from consideration as the result of the restriction/election requirement. Please correct.

Claim(s) 1 is/are indefinite in that in the preamble the claim recites a "polynucleotide comprising" however in section (c) the claim recites "sequences consisting of" These are contradictory in that one (i.e. a "polynucleotide comprising") is open language while the other (i.e. "sequences consisting of") is closed language. As a result the scope of the claimed invention cannot be determined. Please clarify.

35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** The invention was described in –
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

Claim Rejections under 35 USC § 102

10. **Claim(s) 1** is/are rejected under 35 U.S.C. 102(a) as being anticipated by Kikuno et al. (1999).

Claim 1 is drawn to an isolated polynucleotide comprising a sequence selected from a defined group which includes a polynucleotide sequence provided in SEQ ID NO : 365 or the complement of SEQ ID NO: 365 or a sequence that will hybridize to SEQ ID NO: 365 under moderately stringent conditions or a sequence consisting of at least 20 contiguous residues of a sequence provided in SEQ ID NO: 365 or a sequence which has at least 75% identity with SEQ ID NO: 365 or a sequence which has at least 90% identity with SEQ ID NO: 365 or a degenerate variant of SEQ ID NO: 365.

Kikuno et al. teach an isolated polynucleotide comprising (i.e. provided in) SEQ ID NO : 365. See the attached marked Kikuno et al./ SEQ ID NO: 365. Also note the attached marked Emerson et al./ SEQ ID NO: 365. Emerson et al. is not prior art, but it could become prior art if a corresponding US patent issues which claims priority to the US provisional application cited on the front of WO0121640 A1. The sequence taught by Kikuno et al. consists of at least 20 contiguous residues of a sequence provided in SEQ ID NO: 365. Note that because Kikuno et al. teach SEQ ID NO: 365 they necessarily (i.e. inherently) teach the complement of SEQ ID NO: 365 (i.e. a sequence that will hybridize to SEQ ID NO: 365 under moderately stringent conditions)

Also, note that the sequence of Kikuno et al. has a sequence which has at least 75% identity with SEQ ID NO: 365 and has at least 90% identity with SEQ ID NO: 365. Finally, note that Kikuno et al. teach one variant (i.e. degenerate variant) of SEQ ID NO: 365.

11. **Claim(s) 1 and 8** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Sommer et al. (1989).

Claim 1 is drawn to an isolated polynucleotide comprising a sequence selected from a defined group which includes a polynucleotide sequence that will hybridize with SEQ ID NO: 365 under moderately stringent conditions.

Claim 8 is drawn to an oligonucleotide that hybridizes to SEQ ID NO: 365 under moderately stringent conditions.

Sommer et al. teach an isolated polynucleotide (i.e. the first oligo listed in Table 1) which will hybridize with SEQ ID NO: 365 under moderately stringent conditions. Admittedly, the oligo taught by Sommer et al. will not hybridize throughout it entire length with SEQ ID NO: 365 but it will hybridize enough to prime amplification under moderately stringent conditions, therefore it meets all of the limitations of Claim 1 part (d) and all of the limitations of Claim 8. See for example, the sequence of SEQ ID NO: 365 at nucleotide 1359-1361 which reads TAG. This is the inverse complement of the 3' end of the first oligo listed in Table 1. Note that Sommer teaches the minimal homology requirements for PCR primers (i.e. 17-20mers need at least 3 complementary nucleotides at their 3' ends for successful priming). One possible way to overcome this rejection is to amend the claim(s) to make it clear that the sequences claimed in Claim 1, step(d), and Claim 8 hybridize throughout their entire lengths to SEQ ID NO: 365.

35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

14. **Claim(s) 14** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Sommer et al. (1989) as applied against Claim 8 above and further in view of the Stratagene Catalog (1988).

Claim 14 is drawn to a kit comprising at least one oligo according to Claim 8.

Sommer et al. teaches an oligo which meets all of the limitations of Claim 8. Sommer et al. does not teach a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Sommer et al. with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method suggested by Sommer et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

CONCLUSION

15. **Claim(s) 1, 3-4, 8, 11 and 14** is/are rejected and/or objected to for the reason(s) set forth above.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

Ethan Whisenant, Ph.D.
Primary Examiner

Kikuno et al./SEQ ID NO: 365

RESULT 3
AB029000
LOCUS AB029000 4834 bp mRNA linear PRI 04-AUG-1999
DEFINITION Homo sapiens mRNA for KIAA1077 protein, partial cds.
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VERSION AB029000.1 GI:5689490
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SOURCE Homo sapiens brain cDNA to mRNA, clone_lib:pBluescriptII SK plus clone:hj06803.
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE 1 (sites)
AUTHORS Kikuno,R., Nagase,T., Ishikawa,K., Hirosawa,M., Miyajima,N., Tanaka,A., Kotani,H., Nomura,N. and Ohara,O.
TITLE Prediction of the coding sequences of unidentified human genes. XIV. The complete sequences of 100 new cDNA clones from brain which code for large proteins in vitro
JOURNAL DNA Res. 6 (3), 197-205 (1999)
MEDLINE 99397452
REFERENCE 2 (bases 1 to 4834)
AUTHORS Ohara,O., Nagase,T. and Kikuno,R.
TITLE Direct Submission
JOURNAL Submitted (17-JUN-1999) Osamu Ohara, Kazusa DNA Research Institute, Laboratory of DNA Technology; Yana 1532-3, Kisarazu, Chiba 292-0812, Japan (E-mail:cdnainfo@kazusa.or.jp, Tel:+81-438-52-3913, Fax:+81-438-52-3914)
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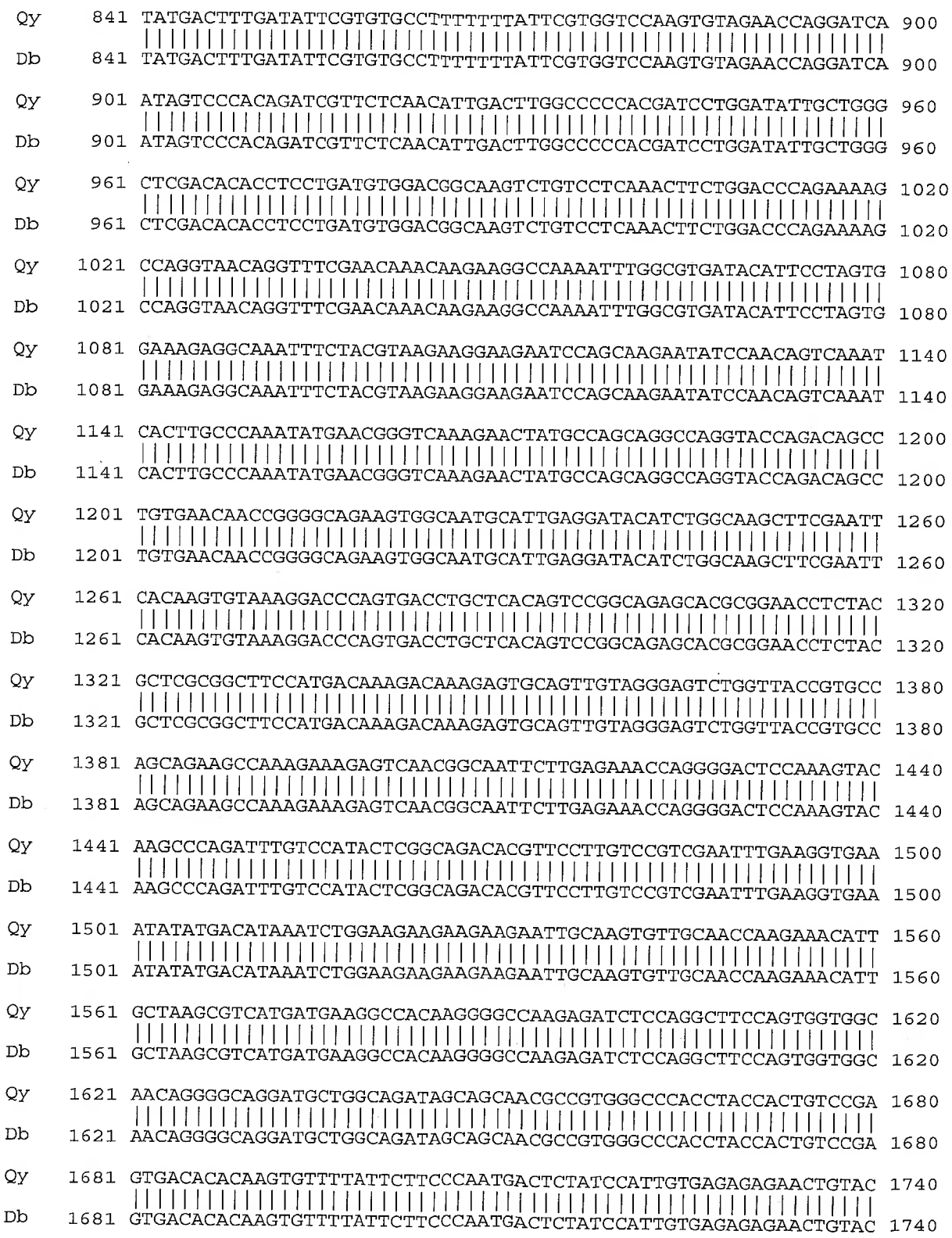
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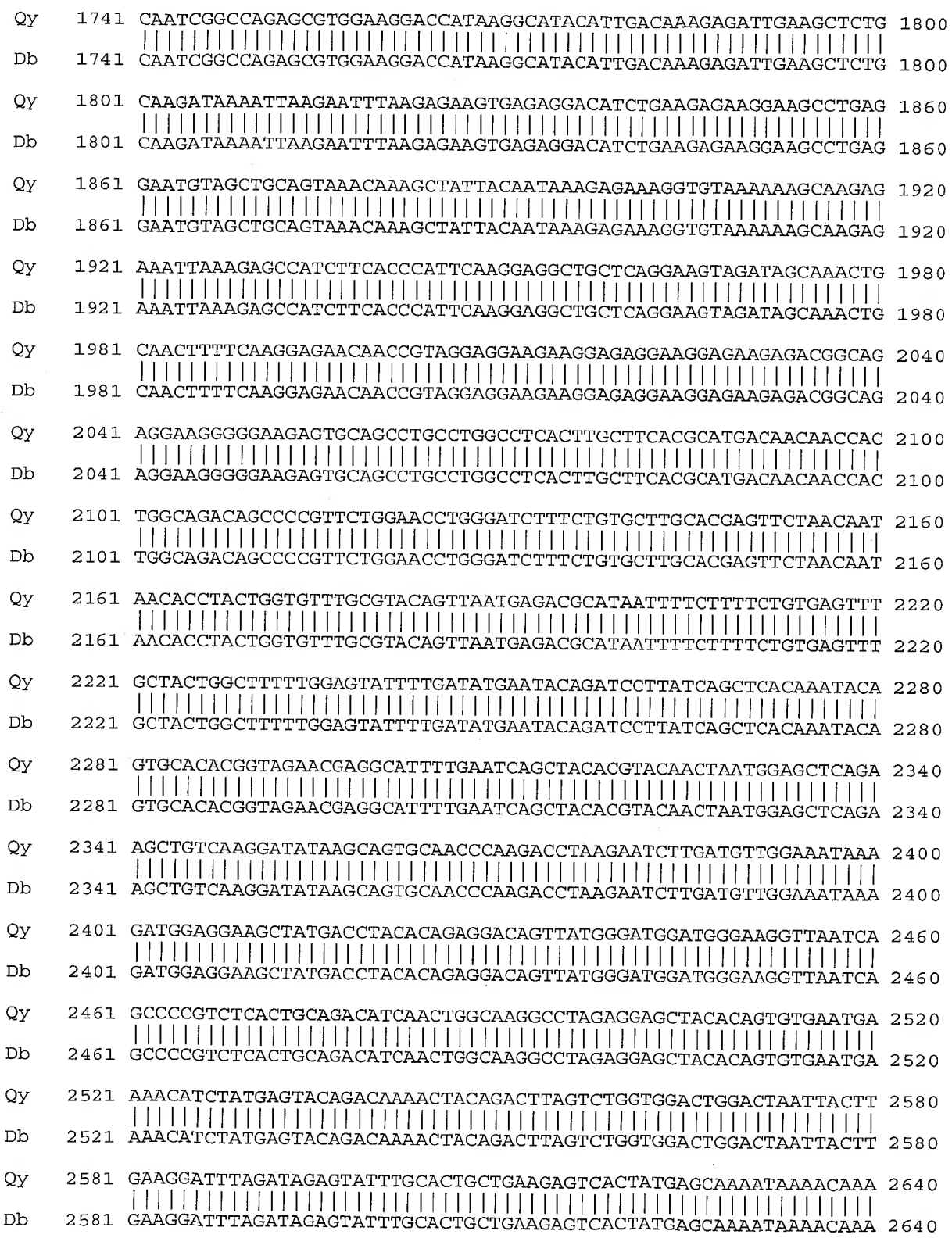
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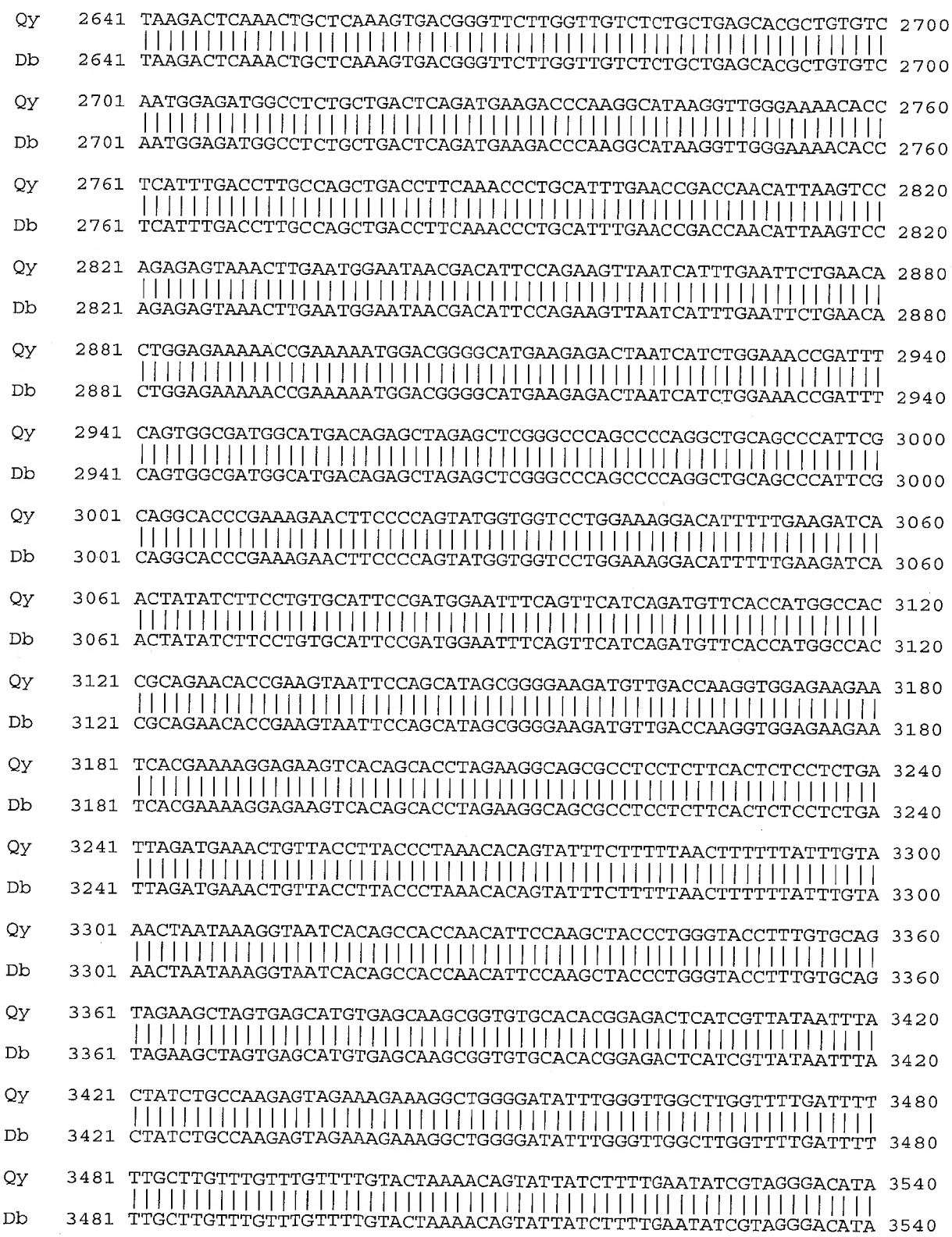
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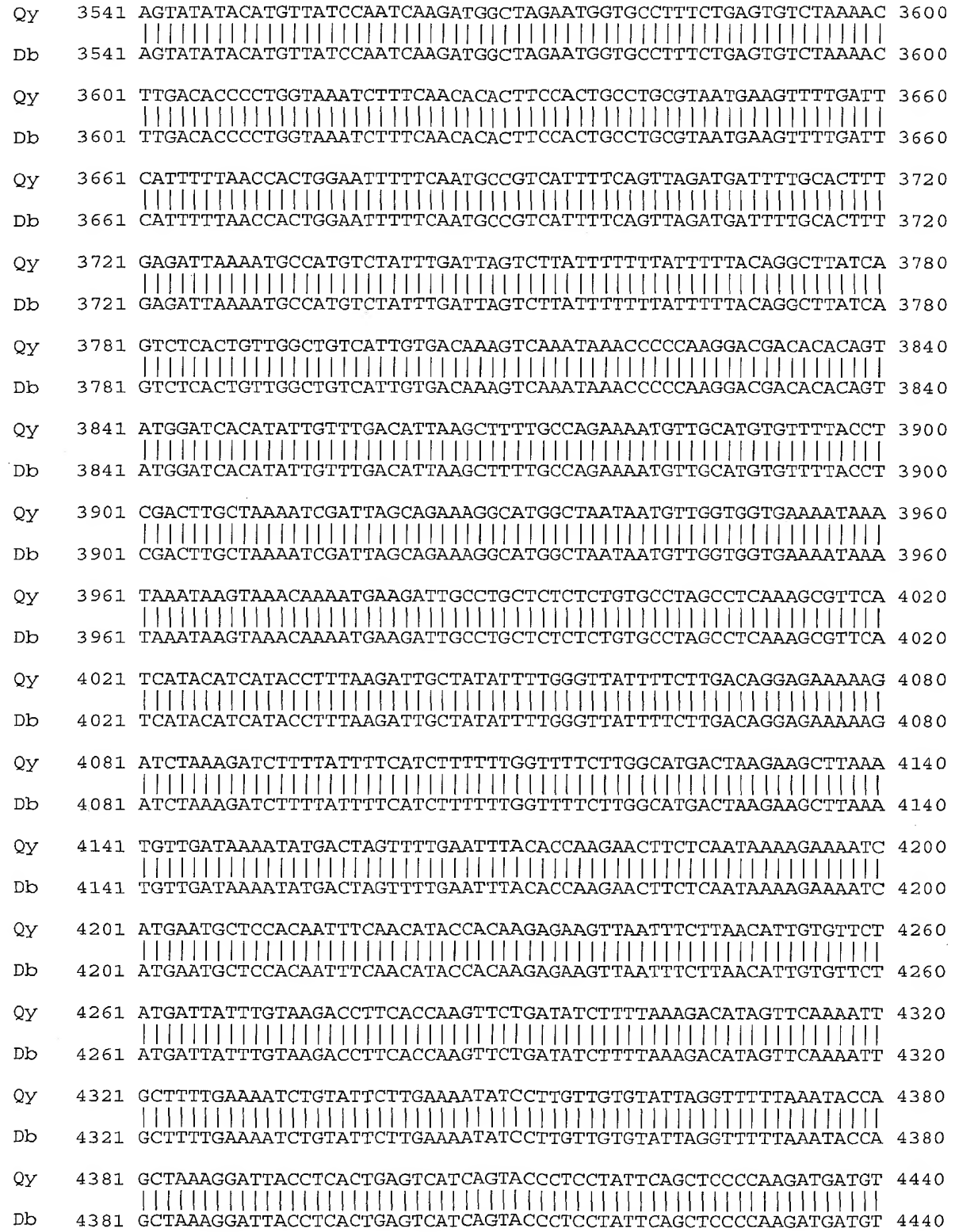
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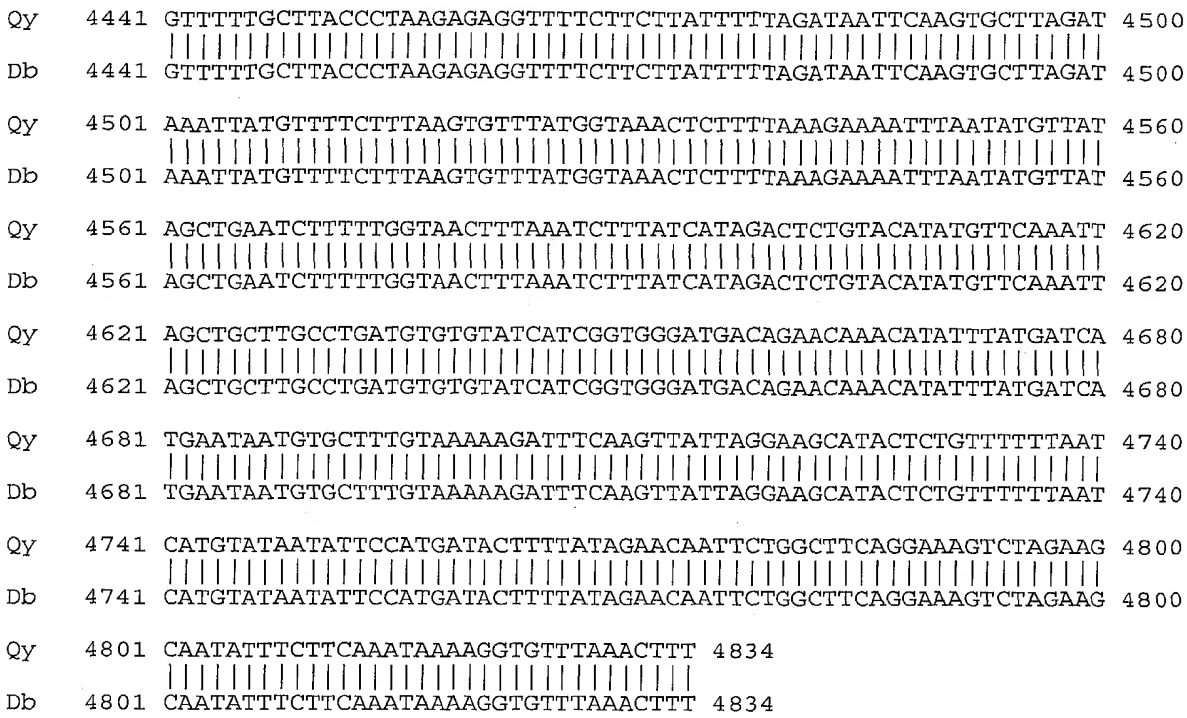
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RESULT 2
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XX
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XX
DT   19-JUN-2001  (first entry)
XX
DE   Human sulfatase (HSulf-1) AB029000 cDNA.
XX
KW   Human; sulfatase; Sulf-1; Sulf-2; cytostatic; virucide; antiinflammatory;
KW   degenerative disease; neural; renal; skeletal muscle; viral infection;
KW   metastasis; inflammation; cancer; EST; Expressed Sequence Tag; therapy;
KW   ss.
XX
OS   Homo sapiens.
XX
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XX
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PR 23-SEP-1999; 99US-0155738.
XX
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PA (ROYA-) ROYAL VETERINARY COLLEGE.
XX
PI Emerson CP, Dhoot GK;
XX
DR WPI; 2001-266062/27.
DR P-PSDB; AAE00438.
XX
PT Novel Sulf-1 or Sulf-2 (members of subfamily of sulfatases) polypeptide
PT useful for treating musculoskeletal, neural or renal degenerative
PT disorder, and for inhibiting viral infection of cells -
XX
PS Claim 2; Page 40-42; 59pp; English.
XX
CC The present cDNA sequence encodes human sulfatase (HSulf-1) which is
CC obtained from EST (Expressed Sequence Tag) AB029000.
CC The invention relates to Sulf-1 and Sulf-2 proteins and their
CC corresponding cDNA molecules which are the members of subfamily of
CC sulfatases. These sulfatase proteins are expressed in neural and muscle
CC lineages in various species. Sulfatase proteins are useful for modifying
CC growth properties of cells, preferably cancer cells, useful in the
CC treatment of cancer and in the inhibition of metastases. Sulf-1 and
CC Sulf-2 are useful in developing cells for transplant in the treatment of
CC skeletomuscular degenerative diseases, neurodegenerative diseases, renal
CC degenerative diseases and in initiation growth of healthy cells and to
CC heal diseased cells in these disorders. Sulfatases are also useful for
CC inhibiting infection of cells by viruses which utilise sulfated heparin
CC proteoglycans for entry into cells, and for modulating recruitment of
CC lymphocytes by cells to sites of inflammation. A functional embryonic

CC technique is useful to functionally characterise members of Sulf-1 and
CC Sulf-2 sulfatase gene subfamily, which is efficient and economical.
XX
SQ Sequence 4834 BP; 1498 A; 992 C; 1042 G; 1302 T; 0 other;

Query Match 100.0%; Score 4834; DB 22; Length 4834;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 4834; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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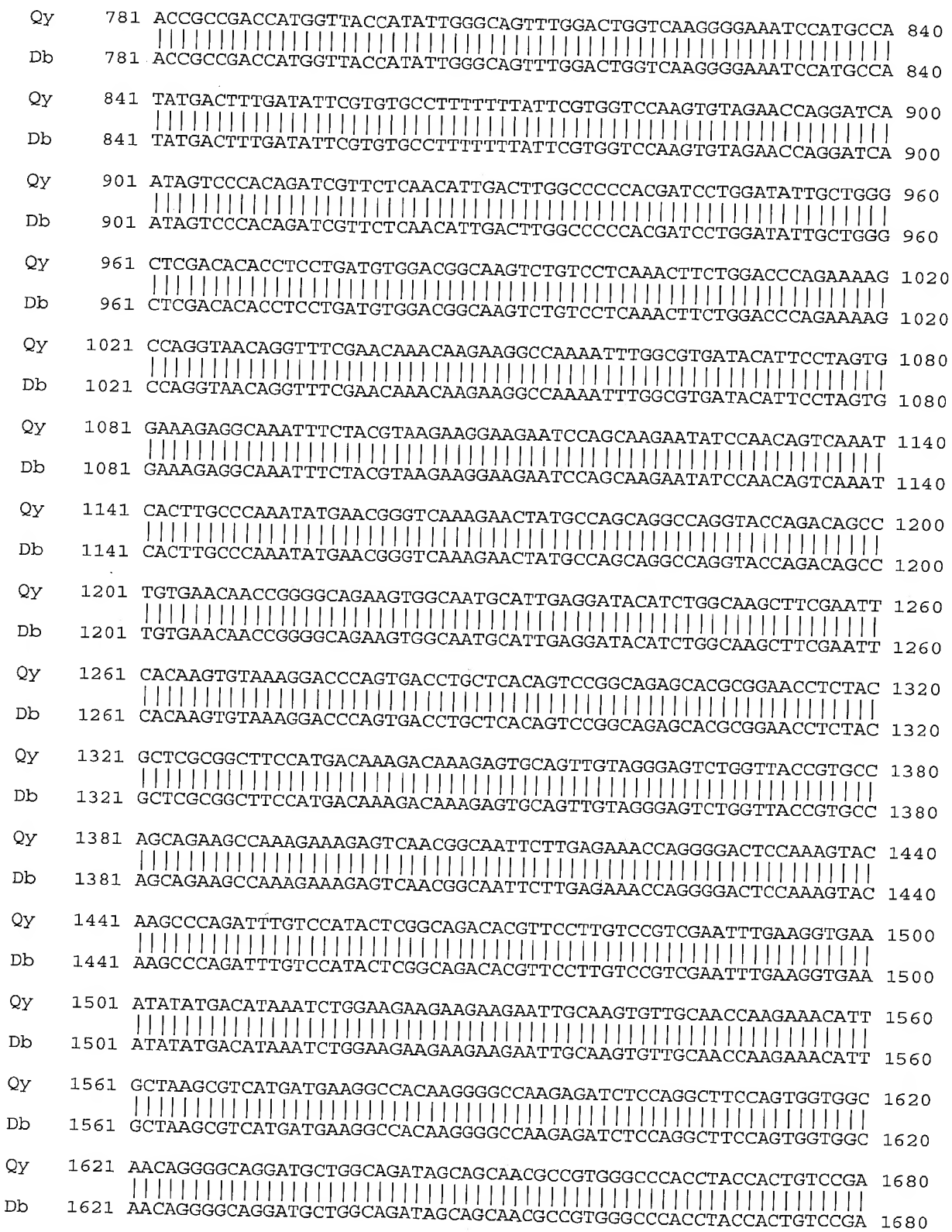
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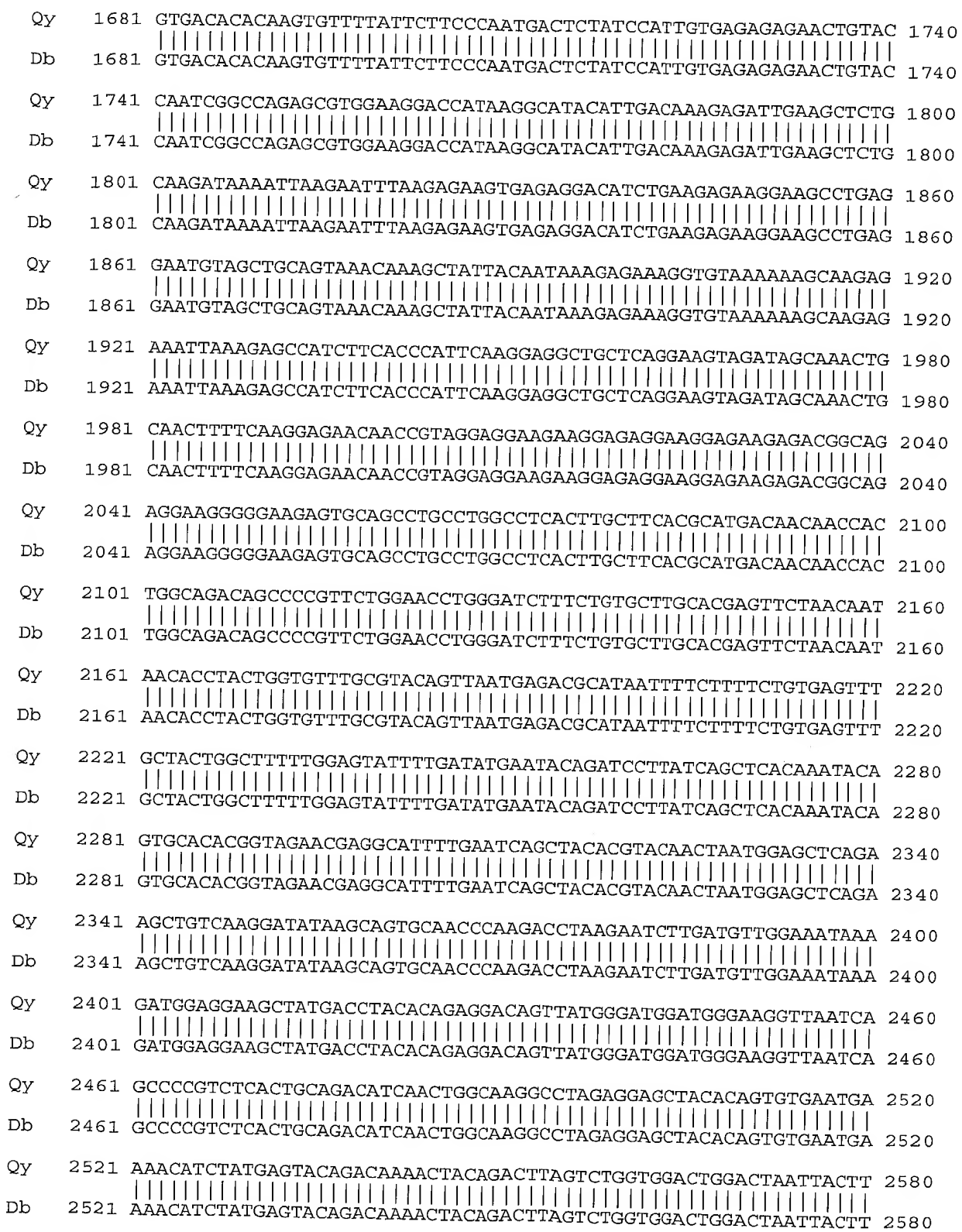
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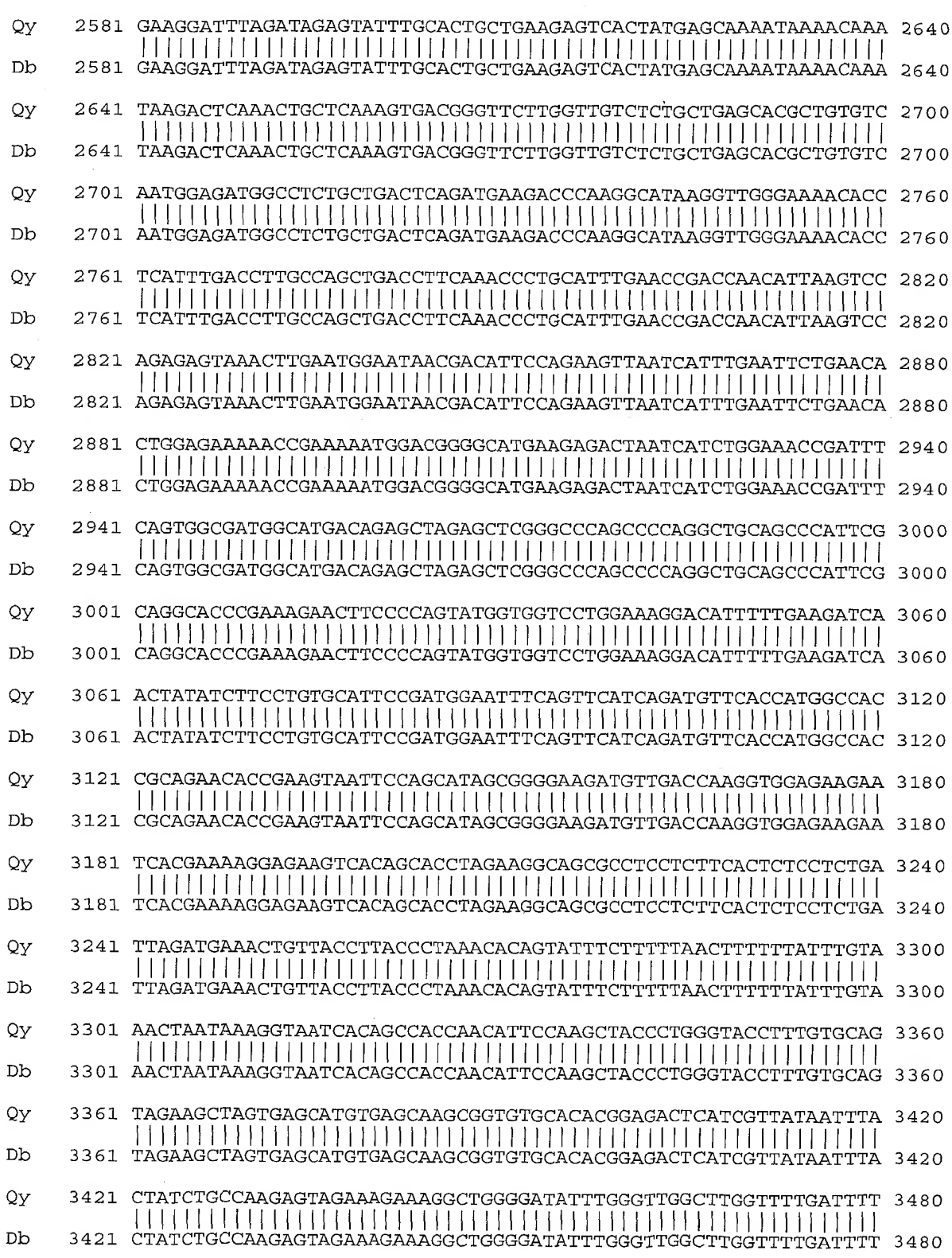
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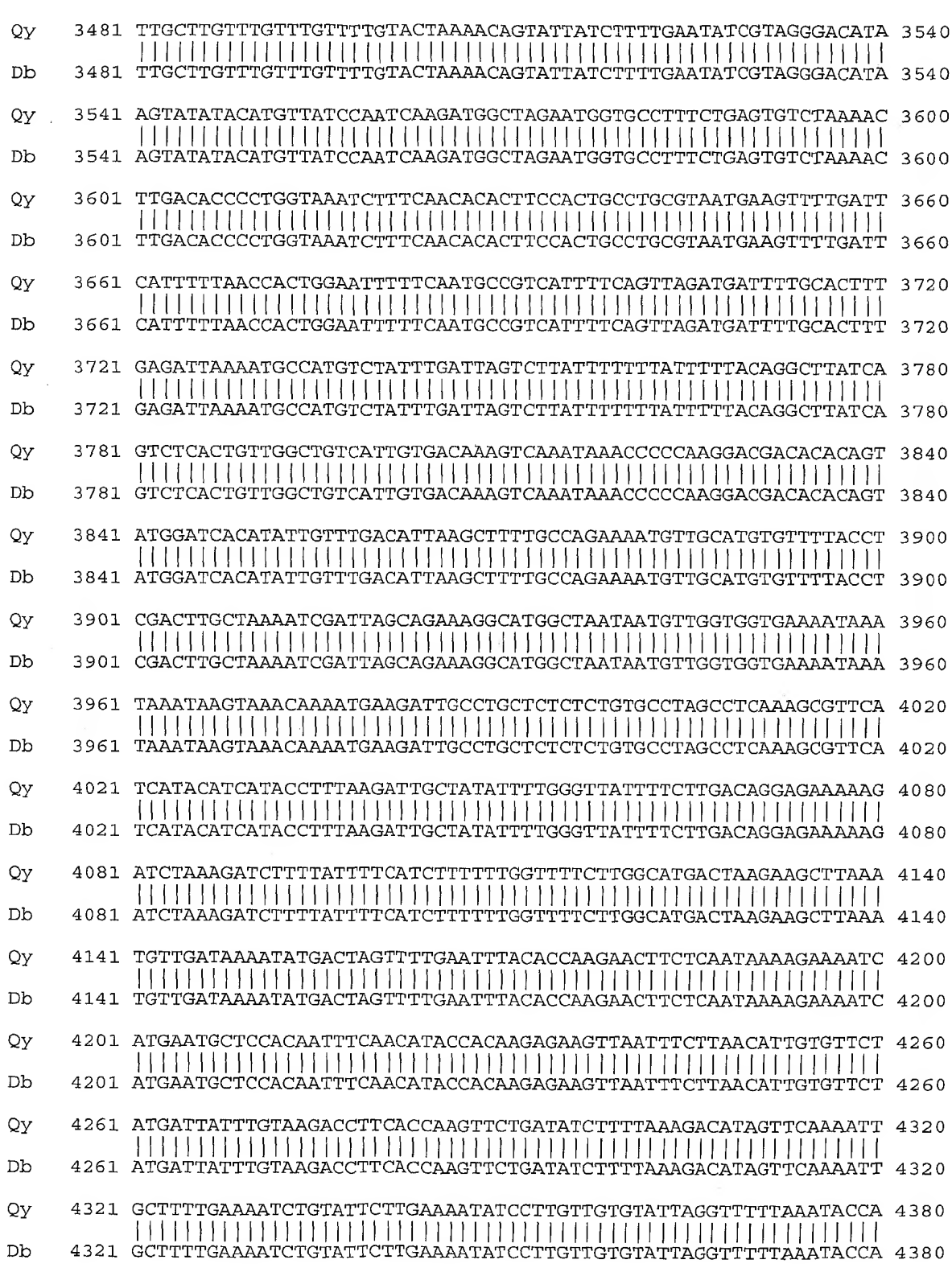
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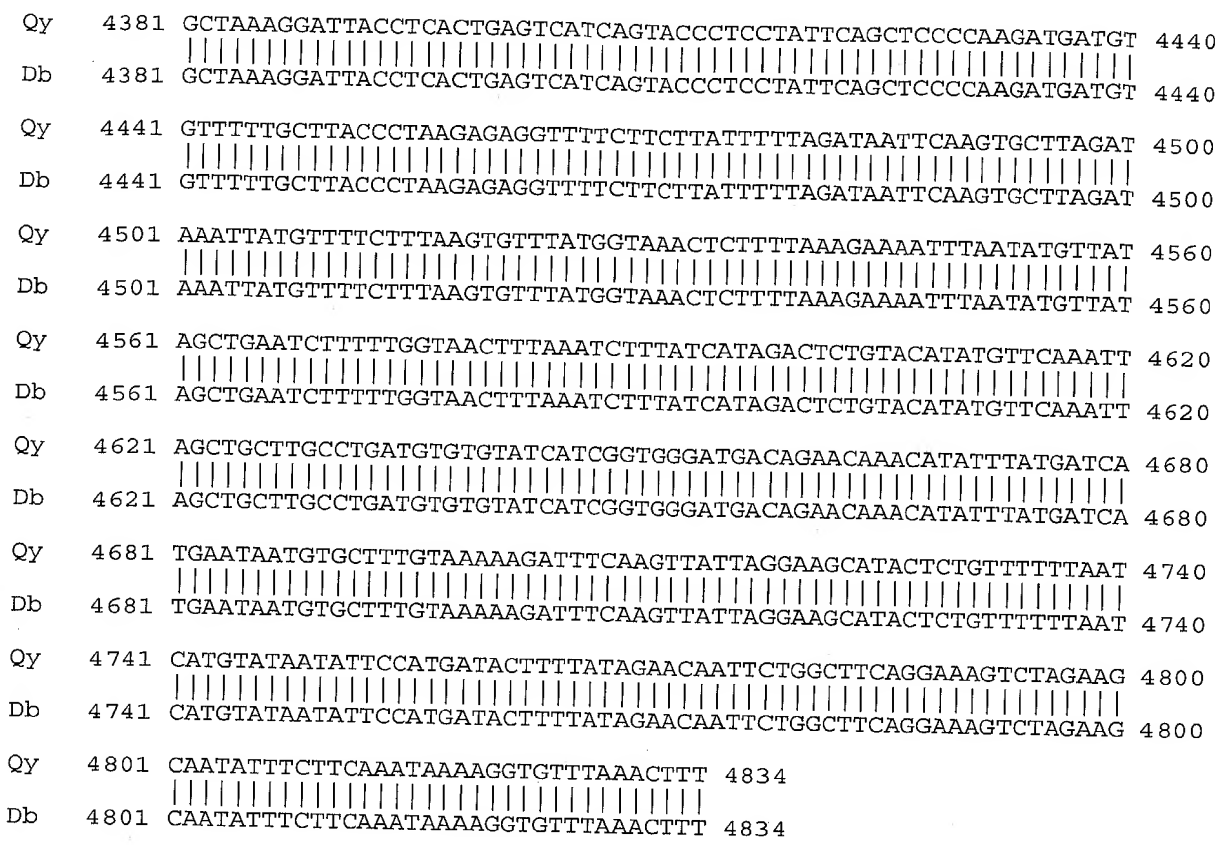
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